

Managing perceived conflicts of interest while ensuring the continued innovation of medical technology

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If it were not for the ongoing collaboration between vascular surgeons and the medical technology industry, many of these advanced treatments used every day in vascular interventional surgery would not exist. The flip side of this coin is that these vital relationships create multiple roles for surgeons and must be appropriately managed.

The dynamic process of innovation, along with factors such as product delivery technique refinement, education, testing and clinical trials, and product support, all make it necessary for ongoing and close collaboration between surgeons and the device industry. This unique relationship sometimes leads to the perception of conflicts of interest for physicians, in part because the competing pressures from the multiple, overlapping roles as clinician/caregiver/investigator/innovator/customer are significant.

To address this issue, the Advanced Medical Technology Association (AdvaMed), the nation's largest medical technology association representing medical device and diagnostics companies, developed a Code of Ethics to guide medical technology companies in their interactions with health care professionals. First introduced in 1993, the AdvaMed Code strongly encourages both industry and physicians to commit to openness and high ethical standards in the conduct of their business interactions.

The AdvaMed Code addresses many of the types of interactions that can occur between companies and health care professionals, including training, consulting agreements, the provision of demonstration and evaluation units, and charitable donations. By following the Code, companies send a strong message that treatment decisions must always be based on the best interest of the patient. (*J Vasc Surg* 2011;54:31S-3S.)

The ongoing collaboration between vascular surgeons and the medical technology industry has made possible many of the advanced treatments used every day in vascular and endovascular surgery. Conversely, these vital and complex relationships create multiple and potentially conflicting roles for surgeons and must be appropriately managed.

The dynamic process of innovation, along with factors such as product delivery technique refinement, education, testing and clinical trials, and product support, all make it necessary to preserve ongoing and close collaboration between surgeons and the device industry. This unique relationship may lead to the perception, and even reality, of conflicts of interest for physicians, in part because the competing pressures from the multiple, overlapping roles as clinician/caregiver/investigator/innovator/customer are significant.

Those of us in health care understand how valuable these relationships are, not only for continued innovation, but also for patient safety. Therefore, it is essential for the vascular surgery community and the device industry to proactively manage the potential for conflicts of interest while promoting the highest ethical standards.

UNDERSTANDING THE ADVAMED CODE

To address this issue, the Advanced Medical Technology Association (AdvaMed), the nation's largest medical technology association representing medical device and diagnostics companies, developed a Code of Ethics to guide medical technology companies in their interactions with health care professionals. First introduced in 1993, the AdvaMed Code strongly encourages both industry and physicians to commit to openness and high ethical standards in the conduct of their business, clinical, and research interactions.

The AdvaMed Code has been revised over the years, most recently in July of 2009, to address new issues and to provide guidance tailored to the unique collaborations in device development. Although the revised *AdvaMed Code of Ethics on Interactions with Health Care Professionals*, is directed at medical technology companies, physicians will also benefit from the enhanced transparency of properly documented principled relationships described in the AdvaMed Code. By adhering to the AdvaMed Code, manufacturers are supporting physicians' obligations to ensure each patient is provided with the highest level of care, by receiving the treatment option most beneficial to their individual needs.

RECENT UPDATES TO ADVAMED'S CODE EXPAND INTO IMPORTANT NEW AREAS, SUCH AS CODE COMPLIANCE

There is a new Code compliance section, under which a list of companies that certify their adoption of the Code are available for public review on AdvaMed's Web site. Companies are asked to certify that they have implemented an

From AdvaMed.

Competition of interest: none.

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effective compliance program consistent with seven elements described in the Office of Inspector General's guidance in the area. Those that certify adoption of the Code are also asked to communicate the principles of the Code to their dealers and distributors with the expectation that they too will adhere to the Code. In addition, they are required to provide contact information for either their compliance department or their anonymous reporting hotlines. This information is also posted on the association's Web site and is intended to facilitate greater communication and accountability in the industry. Finally, because the principles described in the Code are important for the entire industry, companies that are not members of AdvaMed are also able to certify and are listed on the association's Web site as well.

COMPANY-CONDUCTED TRAINING AND EDUCATION

The revised Code includes standards to ensure that company-conducted training and education relating to a product is provided in an appropriate way and in an appropriate setting. Because of the way in which medical technologies are developed and used, companies have a responsibility to ensure that health care professionals are properly trained on the safe and effective use of their products. Often, when dealing with a diffuse population of health care professionals or with nonportable equipment, these training and education programs are held in centralized locations.

THIRD-PARTY CONFERENCES

There is also guidance on the support of third-party educational conferences. These conferences impart valuable information to health care professionals, and companies may provide grants to reduce conference costs or to allow attendance by health care professionals in training. While this support is appropriate, companies should not control the program content, faculty, methods, or materials. The conference sponsor should independently control all of those elements. In all cases, this support should conform to the guidelines of any accrediting body.

ENTERTAINMENT AND GIFT PROHIBITIONS

There is an explicit prohibition in the revised Code on providing entertainment or recreation to health care professionals. Additionally, the changes prohibit gifts of any type, including all noneducational branded promotional items, regardless of value. Items given to health care professionals must be either educational in nature or intended to benefit patients. Examples of educational items include textbooks and anatomical models. An example of patient benefit items is starter kits. It would be inappropriate to provide a health care professional with any item that he or she could use outside a clinical setting, such as an MP3 or DVD player, even if it were originally loaded with educational information.

PROVISION OF MEALS

A new section consolidates the Code's guidance on the provision of modest, occasional meals to health care professionals. Meals, if provided, must be secondary to a bona fide educational, scientific, or business discussion, and should be provided in an appropriate setting. In addition, meals should only be provided to health care professionals with a bona fide interest in the information being presented; meals should not be provided to a health care professional's guests or spouse.

CONSULTING ARRANGEMENTS AND ROYALTIES

Guidance on consulting arrangements with health care professionals has been substantially expanded. Standards in the revised Code include requiring that consulting agreements are for bona fide services; that there is a legitimate need for the services to be provided, that compensation is at fair market value, and above all, that consulting arrangements are not used as an improper inducement for the health care professional's business. There are also guidelines that allow for companies to enter into royalty arrangements with health care professionals in exchange for substantial contributions that improve medical technologies. These payments should not be conditioned on the purchase or recommendation of the product developed, and companies are encouraged to consider the propriety of excluding from the calculation of the royalty payment any products purchased by the health care professional or his or her practice.

EVALUATION AND DEMONSTRATION PRODUCTS

A new section addresses evaluation and demonstration products. This sets forth appropriate parameters under which companies may provide products intended to educate both health care professionals and patients on newer or improved medical technologies. Often, a health care professional will want to evaluate how a particular technology will work in practice before making a significant investment in the technology. A company may provide the item for a reasonable amount of time to allow the health care professional to make that determination. In addition, companies may provide demonstration units, normally not meant for patient use, to educate health care professionals or to allow them to explain procedures to their patients.

OBJECTIVE REIMBURSEMENT INFORMATION

An expanded section addresses the provision of objective reimbursement, coverage, and health economics information to health care professionals to improve patient access to medical technologies.

GRANTS AND DONATIONS

Revised guidance addresses research and educational grants and charitable donations. Companies often support bona fide research and education, as well as legitimate,

beneficial charitable organizations that may require interactions with health care professionals. The Code provides that these grants and donations should not be used improperly to induce business. To achieve this, the Code states that sales personnel should not control or unduly influence the decision of whether a particular health care professional will receive a grant or donation.

Each section is accompanied by a number of frequently asked questions (FAQs). These questions and answers are intended to provide practical, real-world guidance on each section of the Code. While no one can anticipate every ethical challenge or scenario that may arise, the FAQs will help medical technology companies create their own policies and procedures to implement the Code.

PUTTING THE CODE TO WORK

Working with the sales representatives and compliance professionals within the medical technology companies with which you interact will help you to fully understand how the AdvaMed Code impacts your relationship with these companies.

There are also a number of resources available on AdvaMed's Web site available to individuals who wish to

familiarize themselves with the provisions and content of the Code. The newest of these tools provides graphical, easily understood flow charts detailing how a company should approach its interactions with health care professionals under discrete sections of the Code. There are currently three of these tools available and AdvaMed will be adding several more over the course of 2011. Other available materials include template training presentations, detailed comparisons between the prior Code and the revised Code, the ethical codes of other related industries, a useful brochure succinctly explaining the provisions of the revised Code, and translations of the Code into a number of foreign languages. In addition, AdvaMed has developed an online, interactive Code training course. These materials may be accessed at <http://advamed.org/memberportal/Shared/ContentMgt/Templates/OpenDetail.aspx?NRMODE=Published&NRNODEGUID=%7b9234A42C-8E7F-41E6-9DF4-A2E1D0E57F15%7d&NRORIGINALURL=%2fMemberPortal%2fAbout%2fcode%2fdefault.htm%3fWBCMODE%3dPresentationUnpublished&NRCACHEHINT=NoModi#AdvaMed%20Code%20of%20Ethics>

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